1018-49 Assessing a Strategy of Stand-alone Extraction Atherectomy Followed by Staged Stent Placement in Degenerated Saphenous Vein Graft Lesions

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Previously, we reported the high incidence of ischemic complications due to distal embolization (DE) following extraction atherectomy (TEC) of degenerated saphenous vein grafts (DSVG; grafts with lumen ectasia or irregularities comprising ≥50% of the graft length), frequently caused by adjunct PTCA (*Group I*). To assess whether a *staged* strategy (initial stand-alone TEC ± lyric therapy, followed by coumadin and stenting 1–2 months later) could reduce ischemic complications, we performed a pilot study in 28 pts with DSVG (*Group II*). Demographics and graft age (100 ± 47 vs. 99 ± 42 months) were similar, except for more recent MI in Group II (58.3% vs. 22.7%, p = 0.03).

	Group I (n = 44)	Group II (n = 28)
% DS (Pre/Final)	79 ± 14/30 ± 24*	80 ± 17/45 ± 19
DE (%)	22.7**	10.7
Any In-hospital Complications	*11.4%***	*0%*
Death/CABG/MI (%)	6.8/2.3/4.5	0/0/0

DS = diameter stenosis, *p < 0.001, **p = 0.20, and ***p = 0.15 vs. Group II

Preliminary Follow-up: Among 27 pts in Group II eligible for follow-up (>1 month), there were no major ischemic complications. There were 4 total occlusions [1 non-Q wave MI at 4 months and 3 silent occlusions at 6 weeks (1) and 2 months (2)], 9 without clinical indication for additional therapy, 11 staged procedures with stenting (follow-up % DS = 56 ± 30%), and 3 without significant stenosis on follow-up angiography. *We conclude that* this staged angioplasty strategy in degenerated saphenous vein graft lesions: 1) may reduce distal embolization, but *most importantly,* avoids major in-hospital ischemic complications during the initial procedure; but 2) at the expense of ≈15% graft occlusions, which occurred more than 6 weeks after the initial procedure; and 3) prevented any deaths either during the initial procedure or during the follow-up period. These results underscore the importance of early (1 month) follow-up in all patients undergoing this staged TEC, followed by stent procedure in treating complex degenerated saphenous vein graft lesions.

1018-50 Procedural Results and Long Term Clinical Outcomes in Aorto-Ostial Saphenous Vein Graft Lesions After New Device Angioplasty

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Balloon angioplasty of aorto-ostial (AO, ≤3 mm from aorta) saphenous vein graft (SVG) lesions has been associated with suboptimal results and high restenosis frequency. New angioplasty devices are being utilized to treat AO-SVG lesions but comparative efficacy has not been established. Therefore, we compared the early procedural results and late clinical outcomes of 85 patients (90 lesions) treated with the Palmaz-Schatz stent (S) and 34 pts (41 lesions) treated with directional atherectomy (DCA). There was no difference in pt demographics between the 2 groups. TLR = target lesion revascularization, procedural success = final % stenosis >50% and no major complications (death, MI, CABG), and event free survival = freedom from major complications or repeat PTCA at follow-up.

	Stent	DCA	P value
Angiographic Findings:			
Ulceration (%)	16.3	0.0	0.005
Lesion length/Reference size (mm)	8.9±6.0/3.8±0.7	5.3±2.9/3.7±0.7	0.0002/0.8
Acute gain (mm)/Final % stenosis	2.4±0.9/4±7	2.1±0.7/13±14	0.13/0.004
Clinical Findings:			
Major complications (%)	2.4	5.9	0.32
Procedural success (%)	96.5	94.1	0.62
%TLR @ 6/12 months	20.6/32.8	30.8/41.7	0.05
% Event free survival 6/12 months	73.6/52.8	57.8/42.4	0.15

In conclusion: 1) Despite a higher frequency of adverse lesion characteristics including ulceration and longer lesions, S placement achieved improved angiographic results (lower final % stenosis) compared to DCA. 2) Similarly, late clinical outcomes favored S (vs DCA) with fewer TLR events and a higher event free survival. 3) Nevertheless, the overall results of these new device modalities (S and DCA) for AO-SVG lesions are discouraging (<50% 12-month event free survival) and mandate further therapy refinements to improve late clinical outcomes.

1018-51 Histomorphological Features in Primary and Restenotic Plaque Tissue Analyzed by a Relational Database System

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A relational database was developed to enable relational analysis and correlation of clinical data with morphologic changes of the arterial vessel wall. A database system was designed which files all clinical, histological and immunohistochemical data acquired by serial analysis of 177 primary and restenotic tissue specimen obtained by directional atherectomy. The database has been developed in a 4th Dimension (ACIUS, France) environment. Immunohistochemical analysis was performed of cellular and extracellular components with 35 antibodies and the results were added to the database to allow a relational analyzation of pathogenetic depencies. The percentage of positive stained cells in 3 μm thick serial cross-sections of biopsies in a standardized manner (magnification x400, 10 x 10 frames). All values are given as percent of all present cells. Diabetic patients had a significant increase of foam-cells (31%) and collagen I (60%) compared with all other patients (18%, 32%). Smoking and high cholesterol together led to the highest incidence of restenosis (50%; total population: 27%) followed by smoking alone (41%) and was associated with enhanced cellular activation (i.e. high proliferation index and reduction of cytoskeletal filaments). Restenosis had the lowest occurrence of foam-cells (<5%) and a significant reduction of contractile filaments (α-SMC-actin: 65%, desmin: 14%) versus 85% and 54% in all biopsies. Restenosis, diabetes and smoking together was associated with the highest occurrence of proliferation (restenoses 9%, diabetes and smoking 6.1%).

Diabetes was associated with prolonged inflammation and enhanced extracellular matrix content. Determinants of clinical outcome after angioplasty were high cholesterol levels, smoking and cellular activation in primary lesions. (Supported by a grant from Friedrich Baur Stiftung No. 58/94).

1018-52 Volumetric Intravascular Ultrasound Volumetric Analysis Shows that Small Stent Size and Intimal Hyperplasia Contribute to Restenosis

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To explore the mechanisms and patterns of stent restenosis, we performed volumetric intravascular ultrasound analysis (IVUS) in 60 tubular-slotted stents a mean of 8 months after implantation. Motorized transducer pullback (@ 0.5 mm/s within a stationary imaging sheath) permitted measurement of stent and lumen cross-sectional areas in 1 mm axial increments and calculation of stent, lumen, and neointimal hyperplasia (IH = stent – lumen) volumes using Simpson's Rule. Lumen areas were normalized for a reference lumen cross-sectional area to calculate a % area stenosis (AS) for each cross-section. Restenosis was defined as a quantitative angiographic % diameter stenosis ≥ 50 or an IVUS %AS ≥ 75.

	Restenosis (N = 26)	No Restenosis (N = 34)	p
Stent volume (mm^3)	120 ± 41	147 ± 43	0.016
Lumen volume (mm^3)	62 ± 28	118 ± 42	<0.001
IH volume (mm^3)	58 ± 36	29 ± 18	<0.001

We then defined diffuse and focal patterns of restenosis: (1) diffuse = more than 50% of the stent length having a %AS ≥ 75 and (2) focal = less than 50% of the stent length having a %AS ≥ 75.

	Diffuse (N = 6)	Focal (N = 20)	p
Stent volume (mm^3)	120 ± 31	120 ± 44	NS
Lumen volume (mm^3)	36 ± 15	70 ± 26	<0.005
IH volume (mm^3)	84 ± 30	50 ± 34	<0.05

In pts with focal in-stent restenosis, the region of greatest %AS was at the central articulation in 9 (45%), at the stent margins in 6 (30%), and within a stent segment in 5 (25%).

We Conclude: (1) IVUS imaging with automated transducer pullback allows detailed volumetric analysis of in-stent restenosis. (2) In-stent restenosis is due to a combination of reduced stent volume and greater IH. (3) Diffuse in-stent restenosis is seen in less than 1/3 of restenotic stents and is associated with more aggressive neointimal growth than the more common pattern of focal restenosis. Further studies are required to determine if differing patterns of in-stent restenosis are associated with subsequent clinical outcomes.